IBRAMED

QUESTÃO DE RESPEITO

Instructions Manual

SONOFOCUS

Focused Ultrasound 1.8 MHz

Manufactured by IBRAMED
Indústria Brasileira de Equipamentos Médicos EIREILI
Made in Brazil
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SYMBOL DEFINITIONS

BELOW ARE THE DEFINITIONS OF THE SYMBOLS USED ON THE EQUIPMENT AND THROUGHOUT THE INSTRUCTIONS FOUND IN THIS MANUAL. UNDERSTAND THESE SYMBOLS AND THEIR DEFINITIONS BEFORE OPERATING THIS EQUIPMENT.

Caution! Refer to user manual.

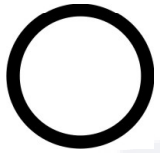
CLASS I Class I Equipment of protection against electric shock.

IPX1 Protected against dripping water.

IPX7 Protected against the effects of immersion.

TYPE BF Electrical Equipment.

Dangerous Voltage.



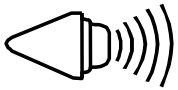
Off switch.

On switch.

Start treatment.

Stop treatment.

Alternating Current.



Transdutor.

SYMBOLS DEFINITIONS

CARTON

Fragile.

This side up.

Limits of temperature for storage and packaging in °C (Celsius Degrees).

Keep away from the rain.

Stacking up.

Do not use if the packaging is damaged.

Refer to operating instructions for correct product use.

Manufacturer’s name and address.

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ABBREVIATIONS GLOSSARY

MHz	Megahertz (million pulses (10^6) by second)
W	Watts
Hz	Hertz
kHz	Kilohertz
cm	Centimeter
cm²	Square centimeter
mm	Milimetro
VA	Volt Amper
min	Minute

These instructions of use allow the user the efficient use of the high intensity focused ultrasound (HIFU) **SONOFOCUS**.
Consult adequate literature in order to obtain additional information about the therapeutic ultrasound before any treatment on a patient. Users must read, understand and follow the information in these instructions of use for each mode of treatment available, as well as the indications, contraindications, warnings and precautions.
The specifications and instructions contained in these instructions of use are valid on the date of their publication. These instructions may be updated at any given time, at the manufacturer's criteria. Visit our website for updates.

ESSENTIAL PERFORMANCE

SONOFOCUS is microcontrolled high intensity focused ultrasound equipment (HIFU) in the frequency of 1.8 MHz ± 10%. Designed for use in aesthetic treatment, it allows a non-invasive modeling of the body contour. The thermal and mechanical cavitational energy produced by **SONOFOCUS** is transferred to the adipose tissue through a curved transducer coupled to the skin with the use of neutral gel. This energy is concentrated in the focal area at a controlled depth (13 ± 3mm) in the subcutaneous adipose tissue, being capable of inducing lipolysis and promoting, by the increase of intracellular tension, discreet rupture in the adipocyte membrane and emulsification of the fat contained in it. The shot time can be adjusted from 1 to 10 seconds with maximum output power of 30 W ± 20% with adjustment of 2 to 30 W.
The equipment must be used only under prescription and supervision of a properly licensed health professional.

PRECAUTIONARY DEFINITIONS

The precautionary instructions found in this section and throughout this manual are indicated by specific symbols. Understand these symbols and their definitions before operating this equipment prior to therapy session.

Text with a "CAUTION" indicator refers to potential safety infractions that could cause minor to moderate injury or damage to equipment.

Text with a "WARNING" indicator refers to potential safety infractions that could cause serious injury and equipment damage.

Text with a "DANGER" indicator refers to potential safety infractions that represent immediately life threatening situations that would result in death or serious injury.

- Read, comprehend and practice the precaution and operation instructions. Know the limitations and dangers associated with the use of any electrical stimulation. Observe the precaution and operation labels placed on this unit.
- Do not operate this unit in an environment where other devices intentionally radiate electromagnetic energy in an unprotected manner.
- Check the cables and connectors before each use.
- The **SONOFOCUS** stimulator is not designed to prevent the penetration of water and other liquids.
- Penetration of water and other liquids may cause malfunction of the internal components of the system, and consequently, promote risk of injure to the patient.
- Disconnect the plug from the power outlet when the device is not used for long periods of time.
- The applicator should be operated only by the handle to avoid exposure to unwanted emission of ultrasound.

WARNING

- In order to be protected from the risk of fire, use only spare fuses of the same type and class.
- Make sure the unit is grounded, connecting it to a grounded power outlet in conformity with the applicable local and national electrical codes.
- Before treating the patient, it is necessary to know the operational procedures for each treatment mode available, as well as the indications, contra indications, warnings and precautions. Refer to other sources to obtain additional information on electrotherapy applications.
- To avoid electrical shock, turn the device off the power supply line before any maintenance procedure.
- The ultrasound treatment must not be applied on swollen infected or inflamed areas, or on skin eruptions such as phlebitis, thrombophlebitis, varicose veins, etc.
- Ultrasound treatment must not be applied on or next to cancerous lesions.

PERIGO

- Patients with neurostimulation devices or implanted pacemakers must be distant from any shortwave diathermy, microwave diathermy, therapeutic ultrasound diathermy, or laser diathermy and must not be treated with these on any part of their bodies. The diathermy energy (shortwave, microwave, ultrasound and laser) may be transferred through the implanted neurostimulation system, and it may cause damage to the tissues, and result in serious injury or death.
- Damage, injury and death may occur during diathermy therapy even if the implanted system is turned off.
- Equipment not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide. Equipment is not the AP or APG category.

INDICATIONS

SONOFOCUS supplies the high intensity focused ultrasound energy and must be used with coupling gel. High intensity focused ultrasound is commonly indicated for aesthetic treatments for a non-invasive modeling of the body contour.

PRECAUTIONS

• Ultrasound must not be applied over sensitive areas or areas with reduced circulation or on anesthetic areas. The patients with reduced sensitivity are not able to warn the professional in case there is any discomfort during treatment, and in patients with compromised circulation, there might be an accumulation of excessive heat in the treatment area.

• Care must be taken in the therapeutic ultrasound treatment of patients with hemorrhagic diathesis or hemorrhagic disturbances.

• Operators must not be routinely exposed to therapeutic ultrasound.

• If a patient complains about deep periosteal pain during an ultrasound treatment, the intensity must be reduced to a comfortable level.

• Heating in the acute or sub-acute phase of arthritis must be avoided.

• Other treatments with electronic devices which may come into contact with the patient during the treatment with therapeutic ultrasound must be properly tested to guarantee the safety of the operation.

CONTRA INDICAÇÕES

• Focused ultrasound must not be applied in areas with subcutaneous adipose layer thinner than 1,5 cm.

• Focused ultrasound must not be applied on pregnant women or over the potentially pregnant uterus.

• Focused ultrasound must not be applied over neoplastic areas or over areas where a tumor has been removed.

• Focused ultrasound must not be applied over the eyes.

• Focused ultrasound must not be used over ischemic areas, where the blood supply may be unable to fulfill the metabolic demand and result in necrosis.

• Focused ultrasound must not be applied over bone epiphyses still in growth.

• It is recommended that any patient with implanted electronic device (e.g. pace-maker, deep brain stimulation device) is not subjected to focused ultrasound therapy.

• Focused ultrasound must not be applied over the cardiac area.

• The focused ultrasound must not be applied over abdominal

CONTRA INDICATIONS

hernia or diastasis of the rectum muscle in patients being treated on the abdomen.

• Focused ultrasound must not be applied in cases of healing deficit.

• The focused ultrasound must not be applied in individuals with metabolic and hepatic diseases which compromise the metabolism of fat.

ADVERSE REACTIONS

• Focused ultrasound may cause a tingling sensation and/or uncomfortable heat.

• **BIOCOMPATIBILITY** of the materials in contact with the patient (ISO 10993-1): IBRAMED declares that the ultrasound transducer and the coupling gel supplied with the equipment do not cause allergic reactions. The transducer and the gel must only be put in contact with the intact skin surface, respecting the limit of time of the duration of this contact, which is 24 hours. There are no risks of harmful effects to the cells, nor allergic or sensitivity reactions. The gel and the transducer (material with which it is manufactured) do not cause skin irritation.

PATIENT POPULATION

• Patients over 12 years old, under this age only by medical prescription or physiotherapeutic indication;
• Patients over 35 kg, under this weight only by medical prescription or physiotherapeutic indication;
• There are no restrictions as of nationality;
• Patients with preserved level of conscience and sensitivity.

CONDITIONS OF USE

• There are no requisites about a maximum level of education for the intended use.
• Regarding the minimum level of knowledge of the user, it is necessary that the user knows the electro physical agents and their therapeutical effects. The user must know physiology, anatomy, and the basic sciences: chemistry, physics, and biology. The user is supposed to have studied or be presently studying physiology and anatomy;
• A maximum level of knowledge is not required from the user;
• The instructions of use are available in Portuguese, Spanish and English;
• Regarding the minimum level of experience of the user, it is necessary that the instructions of use are read carefully and all the instructions are understood before the use of the device;
• There are no admissible deficiencies for the use of the equipment;
• Regarding the frequency of use, this device is used according to clinical needs, up to several times a day and is reusable;
• Regarding mobility, this device is considered a portable device.

Since the introduction of focused ultrasound as a therapeutic resource, over 50 years ago, its biological actions have been investigated. Therapeutic ultrasound is a mode of longitudinal sound energy which, when transmitted to the biological tissues is capable of producing cellular alterations by mechanical and thermal means. Therapeutic ultrasound comprehends a range of frequency which varies from 20 kHz to 5 MHz and its current applicabilities vary according to its frequency, power and the form of transducer. The transducer can be flat (non-focused) or curved (focused) as demonstrated in figure 1.

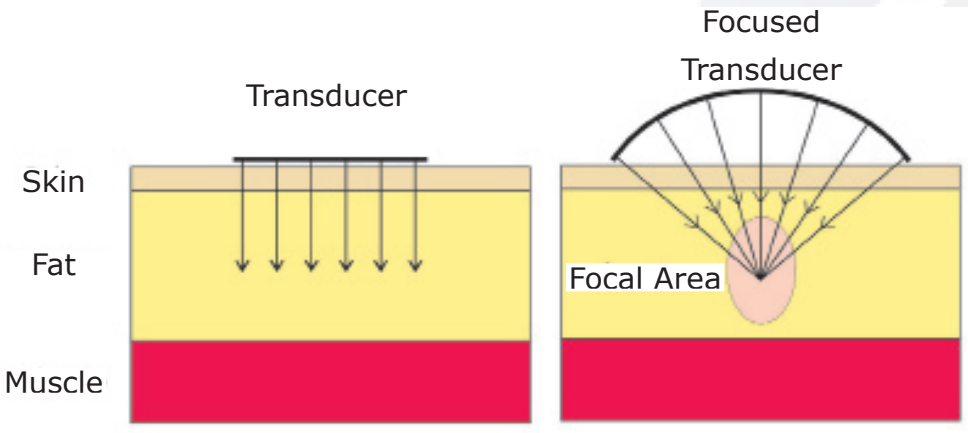

Figure 1. Representative image of flat transducer and focused transducer.

Therapeutic flat ultrasound is a commonly used resource in physiotherapy for physical rehabilitation and uses its mechanic and thermal feats to promote repair and regeneration in bone, muscle and tegmental tissues, as well as helping in the permeation of actives through sonophoresis. In these modes of treatment, low levels of energy are generally used. Also with a flat transducer, but associated with electro therapeutic currents, ultrasound is used in aesthetic treatments including the treatment of cellulitis and localized fat, using high intensities of energy (up to 3 W/cm^2) with the objective of favoring lipolysis, tissue drainage and tissue reorganization.

Focused therapeutic ultrasound - HIFU (High Intensity Focused Ultrasound) was designed for the treatment of tumors by tissue heating and ablation. The first research with this therapeutic proposal dates from 1942, however was only described in humans in 1960. The ability of HIFU to reach cellular volumes at controlled depths appeared as an attractive proposal for use in aesthetic treatments as a non-invasive modeling of the body contour.

HIFU for aesthetic use consist of the propagation of ultrasound propagation through the biological tissues without causing damage, the ultrasound beams carry the energy which converges inside the volume or focal área, which may cause a local increase cavitation and of temperature in a magnitude

sufficient to cause lesion of the subcutaneous adipose tissue with consequent lysis of the adipocytes in the treatment area. This occurs without damage to the tissue in the area around or subjacent.

SONOFOCUS focused lipocavitation has principles similar to those in therapeutic ultrasound and in HIFU. Its transducer was designed to accumulate energy at a depth of 13 ± 3 mm and it works in the frequency of 1.8 MHz ± 10% and maximum power of 30 W. When the adipose tissue in the focal area receives these massive doses of energy, a strong cavitation associated to acoustic shock waves is produced. This combination of mechanic effect associated to the thermal effects produces emulsification of the fat contained in the adipocytes without significantly affecting the adjacent structures. This mixture of mechanic and thermal stress triggers in the adipose cells a cascade of events which induces apoptosis, or programmed cell death. Cells of the inflammatory process (neutrophils and macrophages) are activated and absorb and digest, by liberation of enzymes, part of the lipids liberated and the debris (rests) of the dead cells in the treated area. This inflammatory process is subclinical and generally asymptomatic. The rest of the lipids liberated in the process are dispersed to the interstitial space and diffused to the lymphatic circulation and blood circulation where, theoretically, they are processed by the liver by endogenous lipases and cleaved in free fatty acids and glycerol or form lipoprotein complexes and are liberated in the blood circulation where afterwards they can be used as a source of energy by the cellular metabolism. The increases of circulating plasmatic lipids are considered non-significant and mechanisms of maintenance of homeostasis are activated, promoting their subsequent normalization. In order to enhance the results, we recommend aerobic physical activities after the treatment with **SONOFOCUS**.

RESPONSIBILITY FOR USE ELECTROMEDICAL EQUIPMENT

The use of electromedical equipment is restricted to a physician or under his command, the physical therapists or health professionals properly licensed. The professional will be responsible for properly licensed use and operation of the equipment. IBRAMED makes no representations regarding laws and federal, state or local laws that may apply to the use and operation of any electromedical equipment.

The physician or under his command, also the physical therapist or other professional health care licensed assumes total and full commitment to contact the local certifying agencies to determine any credential required by law for clinical use and operation of this equipment.

The use of electromedical equipment must comply with the local, state and federal country.

SHIPPING DAMAGE

Your **SONOFOCUS** is shipped complete in one carton. Upon receipt, inspect carton and unit for visible and hidden damage. In case of damage, keep all shipping materials including carton and contact the shipping agent responsible for the delivery of the unit. All claims relating to damage during transport should be filed directly with them. The manufacturer will not be liable for any damage during shipping, nor allow for adjustments unless proper formal claim has been filed by the receiver against the carrier. The carton in which your **SONOFOCUS** was received is specially designed to protect the unit during shipping. Please keep all shipping materials in case you need to return your unit for servicing.

Installation Instructions

1.Connect the line cord to the back of the **SONOFOCUS**.
2.Plug the line cord into a grounded wall outlet (100-240V ~ - 50/60 Hz).
3. Plug the ultrasound cables into the correct connections.
4. Switch on your equipment.

CARE WITH YOUR EQUIPMENT

- Avoid places subject to vibration.
- Install the device on a firm horizontal surface, in a place with perfect ventilation.
- In the case of fitted cabinet, make sure there is no obstacle to the free circulation of air in the rear part of the device.
- Do not place the device over rugs, mats, cushions or smooth surfaces which obstruct ventilation.
- Avoid humid, hot or dusty places. This device is not protected against the harmful penetration of water.
- Position the power cable in such a manner that it is free, out of places where it could be treated on, and do not place any piece of furniture over it.
- Do not introduce objects in the orifices in the equipment, and do not place recipients containing liquids over it.
- Do not use volatile substances (benzene, alcohol, thinner, and solvents in general) to clean the cabinet, because they may damage the finish. Use only a smooth cloth, dry and clean.
- The equipment does not need to be used in armored places.
- The equipment must not be used very near or stack over other devices.

- **SONOFOCUS** must not be used without the coupling mean (gel).
- Avoid places subject to vibration.
- Install the device on a flat and firm surface.
- Do not block ventilation.
- Avoid humid, hot and dusty environments.
- Make sure the area around the power cable is free.
- Do not introduce objects in the orifices in the device.

CAUTION

CORRECT EQUIPMENT INSTALLATION PREVENTS SECURITY RISKS

CAUTION

THE EQUIPMENT MAY SUFFER IRREVERSIBLE DAMAGE IF IT WORKS WITHOUT THE ADEQUATE COUPLING MEAN.

ENVIRONMENTAL PROTECTION

The **SONOFOCUS** is an electronic device and has heavy metals such as lead. Thus, there are risks of contamination to the environment associated with the disposal of this equipment and its accessories at the end of their useful lives. The **SONOFOCUS**, parts and accessories must be disposed of as waste. Contact your local distributor for information on rules and laws regarding the disposal of waste electrical, electronic equipment and accessories.

CLEANING THE SONOFOCUS

- Disconnect the system from the power source, wipe with a clean, lint free cloth moistened with water and mild antibacterial soap.
- If a more sterile cleaning is needed, use a cloth moistened with an antimicrobial cleaner.
- Do not place the system in liquids.

CAUTION

THE DEVICE AND ITS CONSUMABLE PARTS MUST BE DISPOSED OF, AT END OF LIFE, ACCORDING TO THE APPLICABLE FEDERAL AND/OR STATE AND /OR LOCAL REGULATIONS.

ELECTRICAL FEED

SONOFOCUS is a protective CLASS I device with applied part type BF of safety and protection. **SONOFOCUS** works in power supply tension in the range of 100-240V~ 50/60 Hz. Just connect the device to the power line and it will perform the selection of power tension automatically. The connector cable to the power supply line is detachable. The device uses the power line plug as a resource to electrically separate its circuits in relation to the power supply line in all poles.

NOTES

In the rear part of **SONOFOCUS** there is a protection fuse. To replace it, **turn the device off the power supply line** and with the help of a screwdriver, remove the protection lid, disconnect the fuse, perform the replacement and reinsert the lid.

Always use the fuses indicated by IBRAMED. Use a fuse for nominal current of 5.0A, operation tension of 250V~ and snap action model 20AG (50A rupture current).

SONOFOCUS does not need any type of power stabilizer. Never use a power stabilizer.

Before turning on **SONOFOCUS** make sure:

- The tension and frequency of the local power supply line of the establishment where the device is installed are equal to the one described on the label describing characteristics of tension and power located at the rear part of the device.
- To prevent electrical shock, do not use the plug in the device with extension cables, or any other types of sockets except the terminals connect perfectly in the receptacle.
- Cleansing and disinfection must always be performed with the power plug off of the power supply line.
- Maintenance and technical assistance of **SONOFOCUS** must always be performed at unauthorized service, only by qualified technicians.

CAUTION

INSIDE THE DEVICE THERE ARE DANGEROUS TENSIONS. NEVER OPEN THE DEVICE.

CAUTION

• This unit is not designed to be used where there is explosion hazard, such as anesthesia departments or in the presence of an anesthetic flammable when mixed with air, oxygen or nitrous oxide.

• Using cables, electrodes and other accessories from other manufacturers and/or different from those specified in this manual as well as the replacement of internal components **SONOFOCUS** may result in increased emissions or decreased immunity of the equipment.

• **SONOFOCUS** equipment is intended for use only by health care professionals. The **SONOFOCUS** may cause radio interference or disrupt equipment operations nearby. It may be necessary to adopt mitigation procedures, such as reorienting or relocating the equipment or shielding of the site.

• Portable and Mobile Radio Frequency (RF) communications equipment can affect Medical Electrical Devices.

POTENTIAL ELECTROMAGNETIC INTERFERENCE

As for the limits of electromagnetic interference, **SONOFOCUS** is an electromagnetic device of Group 1 Class A. The simultaneous connection from the patient to **SONOFOCUS** and to high frequency surgical equipment may result in burns in the ultrasonic transducer application area and possible damage to the device. Short distance operation (1 meter, for example) of short wave or microwave therapy equipment may produce instability in the output of the device. To prevent electromagnetic interference, we suggest that one group of power supply line is used for **SONOFOCUS** and another separate group is used for short wave or microwave equipment. We also suggest that the patient, **SONOFOCUS** e and connection cables are installed at least 3 meters away from short wave and microwave therapy equipment.

Medical Electrical Devices requires special attention regarding Electromagnetic Compatibility (EMC) and must be installed and put into service according to the EMC information provided in the following tables.

Manufacturer's guidelines and declaration – Electromagnetic emissions		
SONOFOCUS is destined to be used in the electromagnetic environment specified below. The user of the equipment should be sure that it will be used in this environment.		
Emission test	**Conformity**	**Electromagnetic emissions**
RF Emissions NBR IEC CISPR 11 IEC CISPR 11	Group 1	**SONOFOCUS** emits RF energy only for its internal functions. However, its RF emissions are very low and it is unlikely to cause any interference in nearby electronic equipment.
RF Emissions NBR IEC CISPR 11 IEC CISPR 11	Class A	**SONOFOCUS** is suitable to be used in all kinds of places other than residential and which are not directly connected to the public distribution of low voltage which supplies the domestic buildings.
Harmonic Emissions IEC 61000-3-2	Class A	
Emissions due to the fluctuation/ scintillation IEC 61000-3-3	Class A	

Manufacturer's guidelines and declaration – Electromagnetic immunity			
SONOFOCUS is destined to be used in the electromagnetic environment specified below. The user of the equipment should ensure that it is used in such environment.			
Immunity Test	**Test level IEC 60601**	**Conformity level**	**Electromagnetic environment – orientations**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV by contact ± 8 kV by air	± 6 kV by contact ± 8 kV by air	The floor should be wooden, concrete or ceramic. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Fast electric transitories / pulse train (Burst) IEC 61000-4-4	± 2 kV in the feeding lines ± 1 kV in the input/ output lines	± 2 kV in the feeding lines ± 1 kV in the input/output lines	The quality of power supply should be that of a hospital environment a or typical commercial building.
Outbreaks IEC 61000-4-5	± 1 kV mode differential ± 2 kV mode common	± 1 kV mode differential ± 2 kV mode common	The quality of power supply should be that of a typical commercial or hospital environment.

Immunity test	**Test level IEC 60601**	**Conformity level**	**Electromagnetic environment -orientations**
Voltage drops, short interruptions and voltage variations in power input lines IEC 61000-4-11	< 5% U (> 95% voltage drops in U) by 0,5 cycle 40% U (60% of voltage drops in U)by 5 cycles 70% U (30% of voltage drops in U) by 25 cycles < 5% U (> 95% of voltage drops in U) by 5 seconds	< 5% U (> 95 % voltage drops in U) by 0,5 cycle 40% U (60% of voltage drops in U) by 5 cycles 70% U (30% of voltage drops in U) by 25 cycles < 5% U (> 95% of voltage drops in U) by 5 seconds	The quality of power supply should be that of a typical commercial or hospital environment. If the user's equipment requires continued operation during power failure, it is recommended the equipment be powered by an uninterrupted power supply or battery.
Magnetic field at power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at power frequency should be at the level of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the C.A. voltage before applying the test			

Manufacturer's guidelines and declaration – Electromagnetic immunity			
SONOFOCUS is destined to be used in the electromagnetic environment specified below. The user of the equipment should ensure that it is used in such environment.			
Ensaio de imunidade	**Nível de Ensaio IEC 60601**	**Nível de Conformidade**	**Ambiente eletromagnético - orientações**
RF Conducted IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	EquipamenCommunication equipment of RF portable and mobile should not be used near any part of **SONOFOCUS** including cable with separation distances smaller than the recommended, calculated from the equation applicable to the transmitter frequency Recommended separation distance: d = 1.2 $\sqrt{P}$ d = 1.2 $\sqrt{P}$ 80 MHz to 800 MHz d = 2.3 $\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum nominal output power in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). It is recommended that the field intensity established by the RF transmitter, as determined by an electromagnetic inspection on the local, [a] smaller than the conformity level in each frequency range [b] . Interference may occur around the equipment marked with this symbol:
RF Radiated IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1: At 80 MHz and 800 MHz it is applied to the higher frequency range.
NOTE 2: These guidelines may not be applicable to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths set by fixed transmitters, such as radio base stations, telephone (cellular / cordless) telephones and land mobile radios, amateur radio, AM / FM radio and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, it is recommended an electromagnetic inspection on the place. If the measure of field strength at the location **SONOFOCUS** is used exceeds the conformity level used above, the unit must be observed to see whether the operation is normal. If an abnormal performance is observed, additional procedures may be needed, such as reorientation or replacement of the equipment.

[b] Over the frequency range from 150 kHz to 80 MHz, the field strength must be less than 3 V / m.

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Recommended separation distances between the communication equipment of RF portable and mobile and SONOFOCUS

SONOFOCUS is intended to be used in an electromagnetic environment in which RF disturbances are controlled. The user of the electro stimulator can help to prevent the electromagnetic interference by maintaining the minimum distance between the portable communication equipment and mobile RF (transmitters) and, **SONOFOCUS** as recommended below, according to the maximum power of communication equipment.

Maximum rated power output of the transmitter maximum nominal potency of transmitter output **W**	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters with a maximum nominal output power not listed above, the recommended separation distance in meters (m) can be determined by using the equation applicable to the frequency of the transmitter, where P is the maximum rated output in watts (W) According to the transmitter manufacturer.

NOTE 1: 80 MHz to 800 MHz, applies to the distance of separation for the higher frequency range.

NOTE 2 These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

SYSTEM SPECIFICATIONS

Dimensions

Width	30 cm (11.8 in)
Depth	30 cm (11.8 in)
Height	11 cm (4.3 in)
Standard Weight (with transducer)	6 kg

Power

Input	100 - 240V ~ 50/60 Hz
Input power	250 VA
Fuses	5A 250 ~ (20AG) Fast Action 50A
Electrical Class	CLASS I
Electrical Protection	TYPE BF

Conformity Regulations

IEC 60601-1

IEC 60601-1-2

IEC 60601-1-4

IEC 60601-1-6

Range of temperature during transportation and storage: 5 - 50 °C / 41 – 122°F.

Range of operational environment temperature:

5-45 °C / 41- 113 °F.

SPECIFICATIONS OF ULTRASOUND

Frequency	1.8 MHz ± 10%
Control mode:	PWM
PWM Frequency:	31 kHz
Shot time:	1 to 10 seconds
Output Power	Maximum 30 W ± 20%
	Adjustable de 2 a 30 W

CONTROLS, INDICATORS AND CONNECTORS

Figure 2. Front view of **SONOFOCUS.**

Figure 3. Rear view of **SONOFOCUS.**

1- ON/OFF key.

2- Light Indicator of "equipment on" condition**.**

3- Display with touch sensitive screen.

4- Connections to pedal.

5- Connections to transducer.

6- Protection fuse.

7- Electrical feed cable connection.

8- Technical characteristics label and serial number.

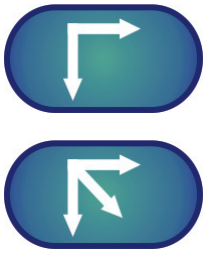
Read and understand these symbols and their definitions before operating the equipment.

POWER - key to select the power of the ultrasound from 2 to 30 W.

SHOT TIME - key to select the ultrasound shot time between 1 and 10 seconds.

AREA - key to select the treatment area between 20 and 400 cm².

The **UP**/**DOWN** keys allow the adjustment of parameters.



Key which allows the adjustment of the numbers of passes according to the number of arrows (2 or 3).

START - key which allows to start the treatment.

STOP - Key which allows stopping the treatment.

MENU - key which allows the access to **INFO** and **LANGUAGE** keys.

INFO - key which allows the access to information referring to indications, contraindications, treatment areas and application techniques.

IDIOMA LANGUAGE - key which allows the choice of language: PORTUGUÊS, ESPAÑOL or ENGLISH.

HOME - key which allows, at any given time, to return to the standard default programming screen.

PREPARING THE EQUIPMENT

Connect the power cable to the rear part of the equipment (figure 4A) and then to the electric power. Press the **ON**/**OFF** key to the position **ON**. Connect the pedal according to figure 4B until you hear a "click". To disconnect just press the button on the top part of the connector and pull. To connect the ultrasound transducer, introduce according to the socket (figure 4C) and turn clockwise until you check its locking.

A

B

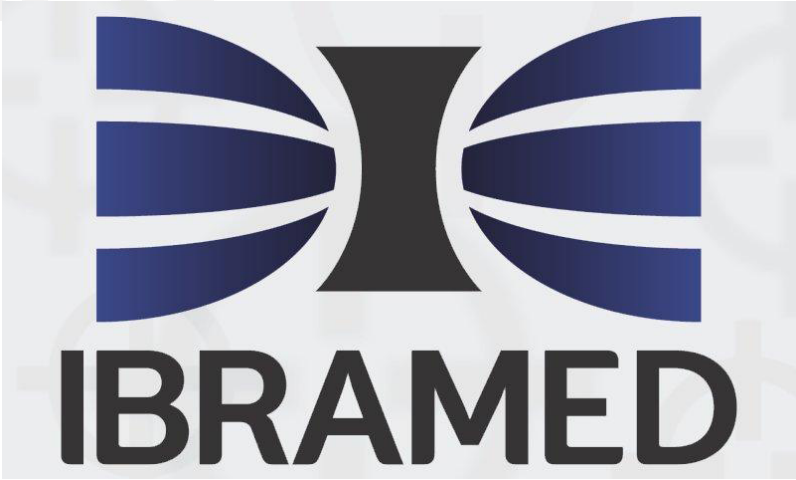
C

Figure 4. A, connecting the power cable; **B**, connecting the pedal; **C**, connecting the transducer.

PROGRAMMING THE EQUIPMENT

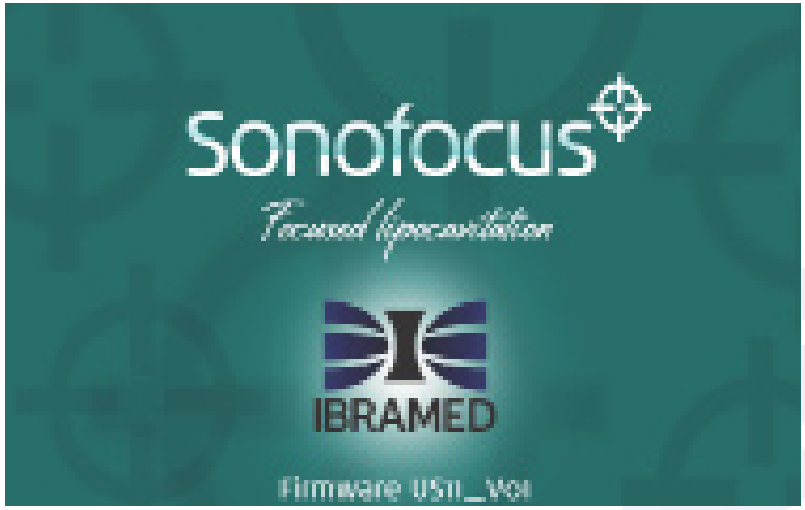
As you turn on **SONOFOCUS** the equipment introduction screens will appear in a sequence (Figure 5A and 5B) followed by the standard default screen of **SONOFOCUS** (Figure 5C).

A



PROGRAMMING EQUIPMENT

B



C

Figure 5. A, Ibramed logo; **B**, equipment and programming firmware model and **C**, standard default screen.

Power

To select the power the user must press the **POWER** key and a suggestion of 22 W power will appear on the screen, as shown in Figure 5C. Using the **UP** and **DOWN** keys this value can be adjusted between 2 and 30 W. To adjust power during application, it is necessary to interrupt the emission, pressing the pedal.

Shot Time

Press the **SHOT TIME** key and using the **UP**/**DOWN** adjust the value between 1 and 10 seconds.

Figure 6. Screen for adjustment of shot time.

Area

Before programming the treatment, the user must demarcate the area and highlight the application points as shown in steps 2 to 5 in Application Techniques (see pages 36 to 37 of this manual).

To program the treatment area press the **AREA** key and using the **UP**/**DOWN** keys adjust the value from 20 to 400 cm².

Figure 7. Screen to adjust the Area.

Number of passes

To program the number of passes press the key with the arrows, the number of passes corresponds to the number of arrows, 2 or 3. If you choose 2 passes, perform the ultrasound shots in the highlighted points marked horizontally and vertically. For 3 passes perform the shots in the highlighted points horizontally, vertically and longitudinally.

Start of therapy

After the necessary parameters are adjusted, for the therapy press **START**. The power chosen, the number of shots and the time of application will appear on the execution screen.

Figure 8. Execution screen.

To start the shots, press the pedal only once. If you wish to stop the application, press the pedal or press **STOP**. In this case, the application and the counting of the shots will stop. To restart the application, just press the pedal once again. To return to the programming screen press **STOP**.

The equipment presents an automatic sequence of shots. During the shots, the image of the active transducer (programmed shot time) or the image of the inactive transducer (fixed intervals at 2 seconds) will appear, as shown in the pictures below:

A

B

Figure 9. A, Active cycle of the transducer and **B**, inactive cycle of the transducer.

After the end of each shot, the equipment will emit a sound signal, at that moment the transducer must be dislocated 1 cm over the treatment area. This dislocation must occur after each sound signal until the end of the programmed number of shots. When the counting of the shots and the application time is finalized, the equipment will emit another sound signal.

CAUTION

Before starting the therapy using SONOFOCUS the cavity of the ultrasound transducer must be completely fulfilled with coupling gel. The volume of gel should be even with the edge of the transducer. Avoid the formation of air bubbles in the gel when filling the transducer.

CAUTION

Never use more than one layer of PVC film in the transducer, because that interferes in the passage of ultrasonic energy leaving it more superficial can cause burns.

TRANSDUCER PROTECTION MESSAGES

TEMPERATURE SENSOR

Integrated to the ultrasound transducer of **SONOFOCUS** there is a temperature sensor which verifies the work temperature of the piezoelectric crystal and consequently the one in the aluminum face. It is a safety mechanism which avoids the overheating of the transducer. In case the transducer reaches the temperature of 41 degrees Celsius, the equipment interrupts the ultrasound emission and the timer for 10 seconds. The professional must keep the transducer coupled, because after 10 seconds the equipment will automatically continue to emit ultrasound.

Figure 10. Warning of excess of temperature.

EQUIPMENT WITHOUT TRANSDUCER

If the equipment is without transducer, when pressing the **START** key, the following image will appear.

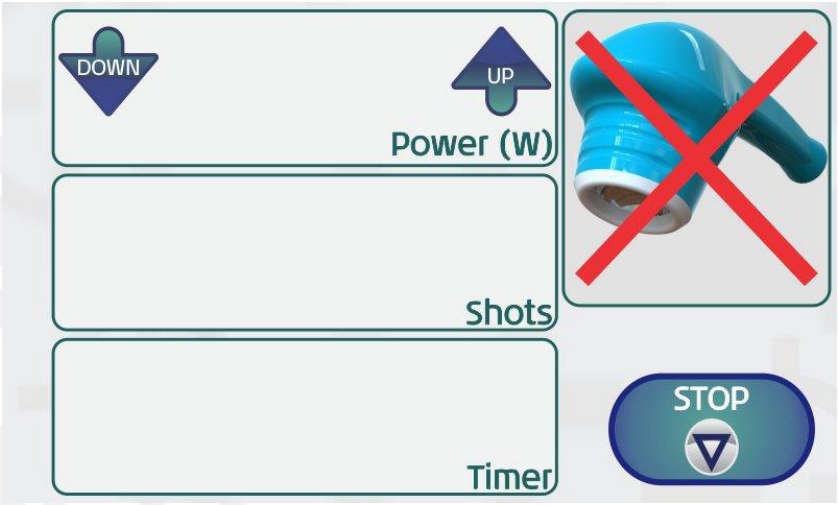


Figure 11. Warning of equipment without transducer.

Just connect the transducer and the message will disappear, and the equipment will go back to the program conditions.

After pressing the **MENU** key, the following screen will appear; which will allow the options **INFO** or **LANGUAGE**.

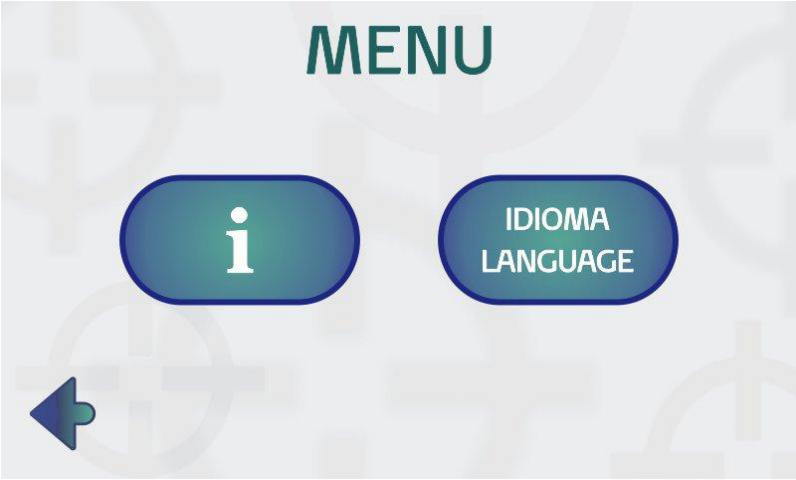


Figure 12. Interactive **MENU.**

USING THE LANGUAGE KEY

The **LANGUAGE** key allows the choice: PORTUGUÊS, ESPAÑOL or ENGLISH, as shown in the screen below:

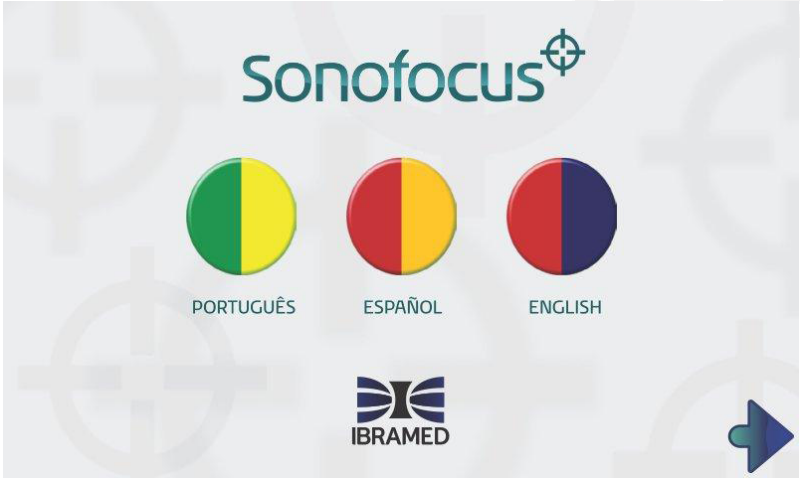


Figure 13. Choice of language.

After selecting the language, the equipment will return to the standard default screen.

USING THE INFO KEY

Using the **INFO** key, the user will have access to the following information: indications, contraindications, treatment areas and application techniques.

Figure 14. INFO key.

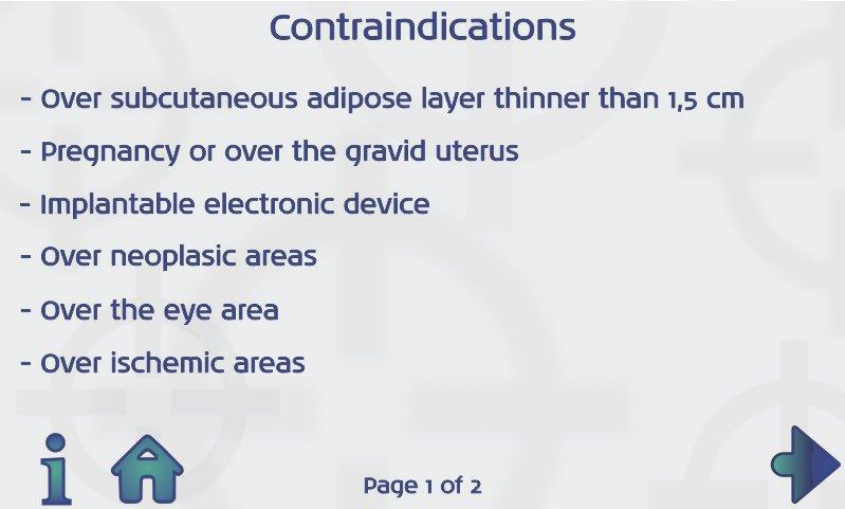
Next are the screens corresponding to each item:

Indications

Figure 15. Indications of use of the equipment.

Contra Indications

A


Contraindications
- Over subcutaneous adipose layer thinner than 1,5 cm
- Pregnancy or over the gravid uterus
- Implantable electronic device
- Over neoplasic areas
- Over the eye area
- Over ischemic areas
Page 1 of 2

B

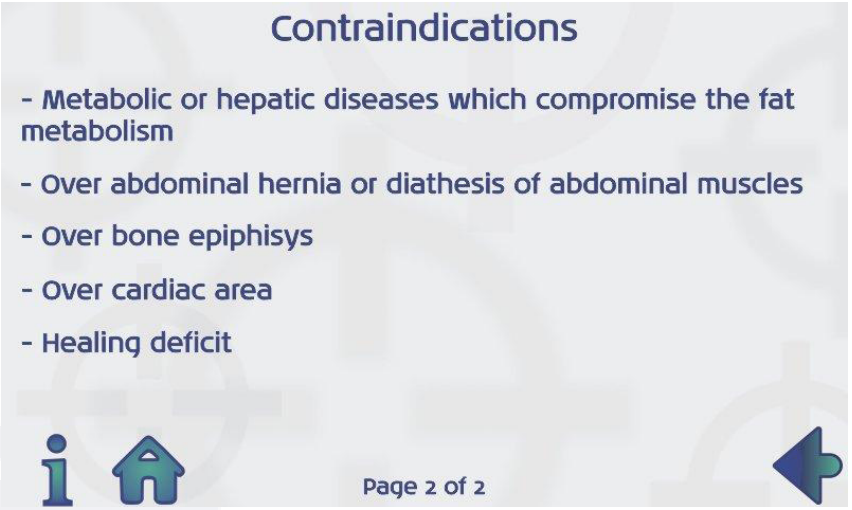

Contraindications
- Metabolic or hepatic diseases which compromise the fat metabolism
- Over abdominal hernia or diathesis of abdominal muscles
- Over bone epiphisys
- Over cardiac area
- Healing deficit
Page 2 of 2

Figure 16. A and **B,** contraindications of use of the equipment.

Treatment Area

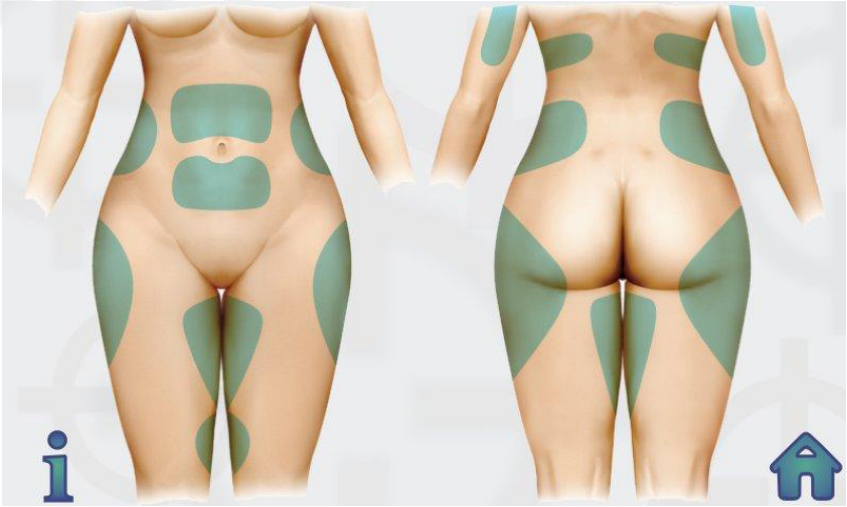


Figure 17. Suggestion of treatment areas.

Application Techniques Screens:

The **Application Techniques** present 11 steps. To follow the step-by-step, the user must use the arrows which appear in the right bottom corner to advance or return. At any given moment, the user can return to the **MENU** using the **INFO** key or return to the default screen using the **HOME** key.

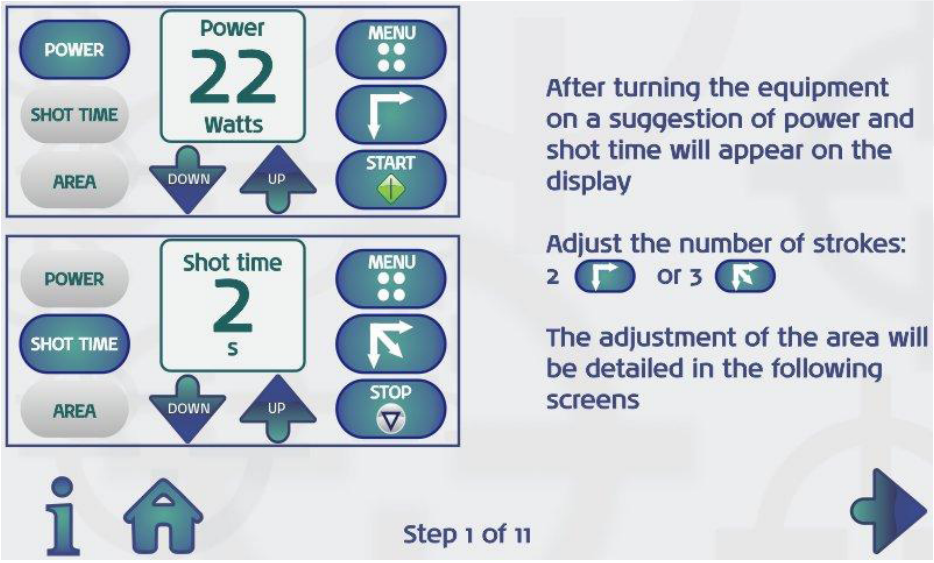


Figure 18. Step 1 of 11.

Figure 19. Step 2 of 11.

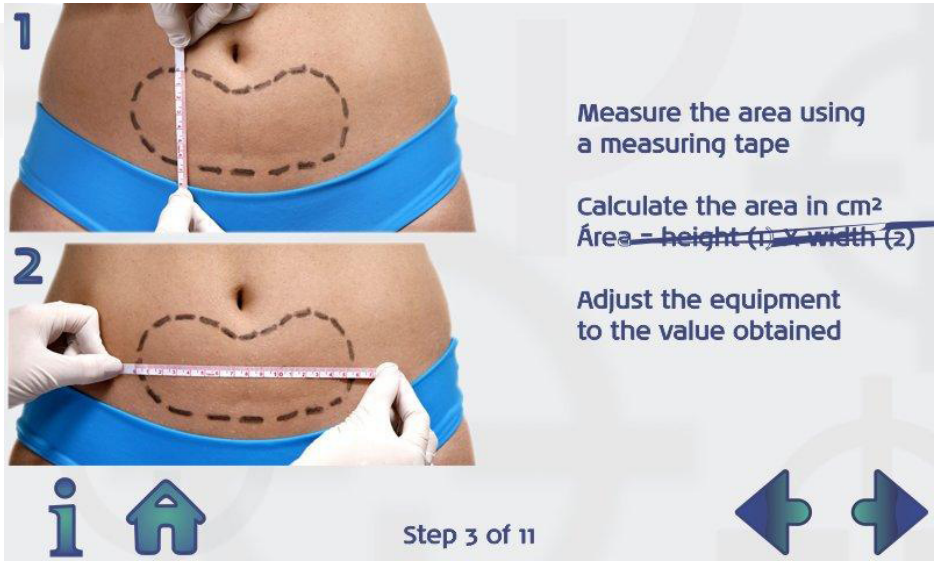

1
2
Measure the area using a measuring tape
Calculate the area in cm²
Área = height (1) x width (2)
Adjust the equipment to the value obtained
Step 3 of 11

Figure 20. Step 3 of 11.

Figure 21. Step 4 of 11.

Figure 22. Step 5 of 11.

Figure 23. Step 6 of 11.

Place the PVC on the transducer
Never use more than one layer of PVC film in the transducer, because that can cause burns
Step 7 of 11

Figure 24. Step 7 of 11.

Figure 25. Step 8 of 11.

Figure 26. Step 9 of 11.

Figure 27. Step 10 of 11.

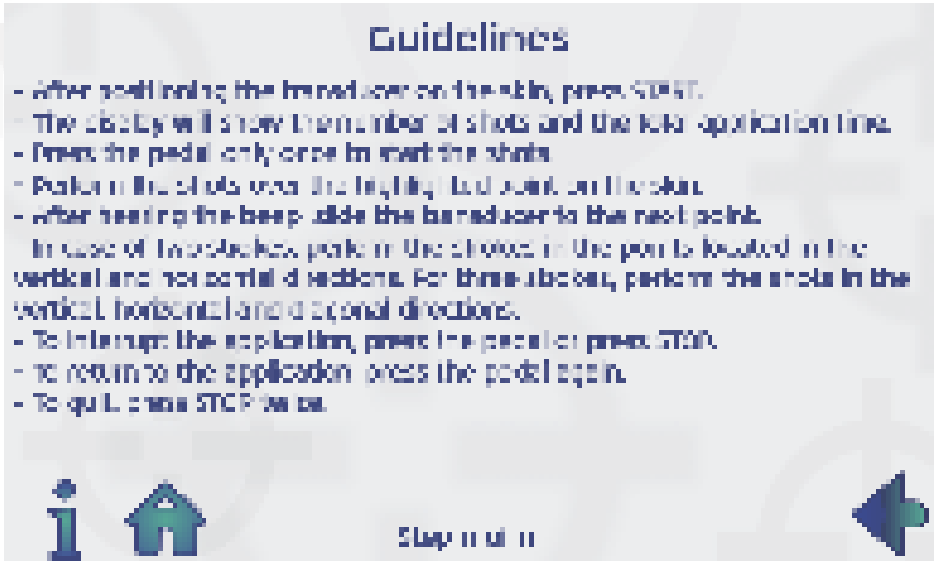


Figure 28. Step 11 de 11.

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Jesus GS, Ferreira, AS, Mendonça AC. Fonoforese x permeação cutânea. Fisioterapia em Movimento 2006; 19(4): 83-88.

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Conselho Federal de Medicina, Resolução Nº 1.711, de 10 de Dezembro de 2003. Disponível em http://www.portalmedico.org.br/resolucoes/cfm/2003/1711_2003.htm

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ACCESSORIES WHICH ACCOMPANY SONOFOCUS

SONOFOCUS contains accessories designed to satisfy the demands of electromagnetic compatibility.

CODE	QUANTITY	DESCRIPTION OF ITEM
03017007	01	I.E.C. 3 X 0.75 X 1500 mm PP FEMALE CABLE
03030039	01	SONOFOCUS METALLIC RACK
03027242	01	POLYPROPYLENE BOARD 20X20 – 0.25 mm - SONOFOCUS
03026084	01	BANNER SONOFOCUS - 0.70 CM X 1.00 METRE
03044009	01	GEL KIT 1 kg (METRIC TAPE, ADIPOMETER, CUVETTE, SPATULA)
02039229	01	PEDAL
02039534	01	SONOFOCUS APPLICATOR
03038047	01	PVC FILM
03019012	01	FUSE 20AG - 05A
03026009	01	PROTECTION FUSE CARD
03040006	01	DIGITAL OPERATION MANUAL IBRAMED- SONOFOCUS

WARNING

• The use of accessories, ultrasound transducer and cables different from those for which the equipment was designed may significantly degrade the performance of the emissions and immunity. Therefore, DO NOT USE accessories, ultrasound transducer and cables from **SONOFOCUS** equipment in other equipment or electromedical systems.

• The accessories and cables described in these instructions of use are designed and manufactured by IBRAMED for use only with the **SONOFOCUS** equipment.

• The **SONOFOCUS** transducer is identified by a serial number; each transducer has its unique characteristics, therefore, its replacement must only be performed by IBRAMED Authorized Technical Assistance.

REPLACEMENT ACCESSORIES

The replacement accessories are designed for use with the **SONOFOCUS**. When ordering, provide the respective codes, description and quantity desired.

The use of accessories, cables and transducer other than those designed for this specific equipment may significantly degrade the performance of the emissions and immunity. Do not use **SONOFOCUS** accessories, cables and transducer in other equipment or electromedical system.

What may initially appear to be a problem not always is really a defect. Therefore, before turning to technical assistance, check the items described in the table below.

PROBLEMS	SOLUTION
The equipment does not turn on 1	Is the power cable properly connected? If it is not, connect it. Also check the power outlet on the wall.
The equipment does not turn on 2	Have you checked the protection fuse? Check if they are **properly connected**. Check also if the value is in accordance with the indicated in the operation instructions.
The equipment is on but does not perform the function.	Have you followed the recommendations and instructions in the operation manual correctly? Check and go over the steps indicated in the item about **controls**, **indicators** and **connections**; and in the item **operation instructions**.

MAINTENANCE

For the safe use of the equipment, we recommended to have it inspected and undergo preventive maintenance at IBRAMED or an authorized technical center **every 12 months**.

IBRAMED manufacturer only assumes liability for the technical features and equipment safety provided the unit is used according to the instructions for use contained in the manual, when maintenance, repairs and modifications are undertaken solely by the factory or authorized agents, and in the event of a breakdown when the components that can cause a security risk to the appliance are replaced by original spare parts. If requested, IBRAMED will provide technical documentation (circuit diagrams, lists of parts and components etc.) necessary for the repair of any equipment.

We assume no responsibility for repairs without prior explicit written permission from IBRAMED.

WARRANTY

IBRAMED, Indústria Brasileira de Equipamentos Médicos EIRELI, here identified to the consumer through the following address and telephone number: Av. Dr. Carlos Burgos, 2800, Jd Itália, Amparo/SP; Tel.: 55 19 3817 9633 provides product-warranty for eighteen (18) months insofar as the conditions set for warranty terms are followed by the user as mentioned below.

WARRANTY TERMS

1) IBRAMED warrants that this product is free of manufacturing defects for eighteen (18) continuous months provided the set terms presented in these instructions for use are followed.

2) The warranty period takes effect from the date of purchase and applies to the original purchaser only, even in the event of a product being transferred to a third party. The warranty covers the replacement of component parts and labor required to repair defects whenever the presence of such manufacturing defects can be determined.

3) Customer Service during the warranty period will be provided exclusively at IBRAMED sale points by IBRAMED itself or another agent designated by the manufacturer.

4) The warranty does not cover damage caused to the product resulting from:

a) Failure to follow the specifications and recommendations detailed in these instructions for use during installation or use of the product.

b) Accidents or acts of God, connections to electrical system with inappropriate voltage and/or subjected to excessive fluctuation or overcharge.

c) Misuse, lack of reasonable care, product alterations, modifications or repairs undertaken by individuals or entities not authorized by IBRAMED.

d) Removal or adulteration of the equipment serial number.

e) Damage during Transport.

5) The legal warranty does not cover: expenses incurred during product installation or transport to the plant or sale point, labor, materials, parts and adjustments necessary to the readiness of the premises in view of the installation of the device, such as but not limited to electric net, masonry, hydraulic network, grounding system, as well as their requirements.

6) The warranty does not cover parts subjected to natural wear, such as but not limited to control keys, control

keys, handles and moving parts, cables, connectors, device cabinets.

7) The selling points are neither authorized to alter the conditions mentioned in this document nor to take any commitment on behalf of IBRAMED.

DANGER

Do not alter this equipment. Any unauthorized modification can affect the safety of this equipment.
Never make unauthorized repairs.

TECHNICAL ASSISTANCE

If you have any doubts or problems related to the operation of your equipment please contact our technical department. Call: **19 3817.9633.**

Company authorization of operation: 103.603-1

Technician in Charge: Maicon Stringhetta

CREA-SP: 5062850975

CEFAI – IBRAMED Center for Education and Advanced Training

IBRAMED Equipment goes beyond technology. It also provides knowledge! Science constitutes our differential value and we effectively take advantage of its benefits in order to ensure patient safety and thereby maximize results.

IBRAMED develops products with scientific support of the most recent medical studies published in major scientific journals in the areas of biological, health and exact.

Access to the knowledge database is guaranteed by CEFAI (IBRAMED Center for Education and Advanced Training) whose goal is to provide technical and scientific support as well as current literature on therapies and their applicability while our treatment choices are always thoroughly selected according to the best and latest clinical criteria. CEFAI takes into account the personal and professional development of all its partners and customers.

CEFAI invites both students and professionals in the fields of Physical Rehabilitation, Esthetics, Physiotherapy, Dermatology and Esthetic Medicine to take part in free courses, workshops, and the best Postgraduate *Lato Sensu* courses in the areas of physical rehabilitation and esthetics.

Special attention is also given to those interested in visiting our structure. Whatever your professional development needs, we'll be right by your side to provide you with unconditional support.

We are happy to assist you!

Contact – **cefai@conexaocefai.com.br**
www.conexaocefai.com.br
+55 19 3808. 2348

Thanks,

IBRAMED – Matter of respect!

IBRAMED

QUESTÃO DE RESPEITO

IBRAMED
Indústria Brasileira de Equipamentos Médicos EIRELI
Av. Dr. Carlos Burgos, 2800 - Jd. Itália
13901-080 - Amparo - SP - Brasil
55 19 3817 9633
www.ibramed.com.br
ibramed@ibramed.com.br